# Balloon Catheter

## Description

This invention relates to a balloon catheter according to the preamble portion of claim 1.

Such a catheter is referred to as a so-called "over-the-wire catheter". This catheter construction comprises a catheter shaft having an inflatable balloon at its distal end. At the opposite proximal end, normally a connecting piece is arranged. Further, the known catheter comprises a guiding wire extending through a guiding wire lumen of the catheter shaft from the proximal end to the distal end and through the balloon. Finally, an inflation or deflation lumen is provided in the catheter shaft, said lumen extending from the proximal end of the catheter shaft to the balloon. Air or liquid may be supplied or discharged through said lumen for expanding the balloon.

If such a balloon catheter is to be inserted into a heart artery, an outer guiding catheter is at first pushed with its curved tip through the aorta, usually starting from the thigh, to the heart artery to be treated, in which e.g. a stenosis exists, which shall be expanded by the balloon catheter and possibly stabilized by a simultaneously implanted stent. The tip of the guiding catheter is thereby temporarily fixed in the region of the branching of the heart artery to be treated from the arch of the aorta. Into said guiding catheter, the guiding wire is subsequently inserted until its tip has passed the stenosis. In the following, the catheter shaft of the balloon catheter is inserted through the guiding wire into the aorta and the vessel to be treated, until the balloon stops in the region of the stenosis.

For this type of balloon catheter, the guiding wire must have approximately the double length of the catheter, as the catheter at first has to be threaded on the guiding wire outside the patient's body.

In a further known balloon catheter construction, a catheter shaft is provided having a shaft portion extending from the connecting piece and being composed of metal, which has a full cross section except for the inflation. Said portion (also referred to as hypotube) is followed by a plastics portion extending to the balloon in which a guiding wire volume is provided besides the inflation volume, which, however, has an outlet opening in front of the metal shaft portion, said outlet opening being positioned relatively close in front of the balloon. This makes it possible to use a substantially shorter guiding wire. In addition, this type of catheter shows a higher stiffness due to the metal shaft portion disposed in the proximal region, which enhances the so-called pushability.

It is an object of the present invention to provide a balloon catheter of the type as mentioned in the preamble portion of claim 1, which makes in possible to create an over-the-wire catheter having a higher pushability.

This object is solved by the features of claim 1.

Due to the fact that the inventive catheter has a catheter shaft portion the length of which is selectable and which extends from the proximal end, said portion being provided with a reinforcing pipe, there results at first a clearly enhanced pushability and the advantage that the friction between the guiding wire and the catheter shaft is clearly decreased. This makes the handling of the inventive catheter much more easier. It is also preferred to cover the inner periphery of a reinforcing pipe made of metal, preferably steel, with a

coating which further decreases the friction, e.g. a coating made of PTFE.

The sub-claims relate to advantageous embodiments of the invention.

In a particularly advantageous embodiment of the inventive catheter having a metal reinforcing pipe, the metal pipe may be covered inside with a coating in order to decrease the static and dynamic friction for the guiding wire. Said coating may consist of plastics, e.g. polyethylene, PTFE or Teflon.

For the purpose of coating, it is possible to mount a plastics tube, e. g. made of polyethylene, having a diameter slightly larger than the inner recess of the reinforcing pipe onto a stiletto, with or without an influence of heat, until the outer diameter of the tube is smaller than the inner diameter of the metal reinforcing pipe. The tube is introduced to the inside with the help of the stiletto and applied to the inner wall of the reinforcing pipe by a longitudinal heating due to the corresponding expansion of the pipe. Both ends of the tube are twisted off or cut off after removal of the stiletto.

In a further, particularly advantageous embodiment, the plastics tube may be cross-linked with radiation before removal, in order to achieve a better restoration of the tube in the reinforcing pipe.

In a further embodiment, the surface of the plastics tube is modified prior to its insertion into the metal reinforcing pipe for increasing the adherence at the inner wall, e. g. by plasma treatment or corona treatment.

In addition, the tube for the plastics coating may be co-extruded from e. g. polyethylene and provided with a outer

adhesive layer made e. g. from ethylene vinyl acetate (EVA) or nylon.

In an alternative embodiment, the plastics tube is melted onto the inner wall of the metal reinforcing pipe using heated compressed air.

In order to obtain a better joining of the reinforcing pipe and the plastics coating, an adhesive may additionally be introduced between the inner wall of the reinforcing pipe and the tube along the overall length of the reinforcing pipe or at its ends.

In a further embodiment, it is possible to allow the inner coating to exceed the portion of the metal reinforcing pipe to cover also the adjacent portion of the plastics pipe. In an extreme case, it is possible to coat the complete inner wall of the metal reinforcing pipe and the adjacent plastics pipe.

All in all, the coatings first and foremost serve to decrease the friction between the inner wall of the respective pipe portion and the guiding wire.

In order to avoid kinks, it is further possible to provide a nylon tube coating in the transitional region between the metal reinforcing pipe and the plastics pipe.

Other details, features and advantages of the invention result from the following description of the drawings, wherein:

Fig. 1 is a schematically simplified view of the principle of the inventive catheter;

Fig. 2 is a sectional view along line A-A;

Fig. 3 is a sectional view along line B-B, and

Fig. 4 is an enlarged view of detail X.

In Fig. 1, a balloon catheter 1 is disclosed. The catheter 1 comprises a catheter shaft 2. An inflatable balloon 4 is provided at the distal end 3 of the catheter shaft 2. A connecting piece 6 is provided at the proximal end 5 of the catheter shaft 2.

Furthermore, Fig. 1 shows a guiding wire 7 extending through the connecting piece 6 into a guiding wire lumen 8 of the catheter shaft 2 from the proximal end 5 until the distal end 3 and through the balloon 4.

In addition, an inflation or deflation lumen 9 is provided, which extends from the connecting piece 6 through the catheter shaft 2 until the balloon 4.

As shown in Fig. 1, the catheter shaft 2 comprises a portion 10 extending from the proximal end 5, said portion being provided with a reinforcing pipe 11 made of metal or plastics. It is also possible that the reinforcing pipe is made of metal and is provided with an inner coating made of plastics, preferable for decreasing the friction.

Fig. 2 shows a cross-sectional view explaining the concentric arrangement of the aforementioned lumen 8 and 9 as well as the pipes 12 and 13 limiting said lumen. In this portion of the catheter shaft 2, the pipes 12 and 13 are formed as plastics pipes, wherein the lumen 9 is disposed between the pipes 12 and 13 and the lumen 8 is disposed within the pipe 13 through which the guiding wire 7 is passed.

Fig. 3 explains the sectional view along line B-B in Fig. 1. Herein, the reinforcing pipe 11 made of metal, preferably steel such as stainless steel, is shown, said reinforcing pipe being surrounded by the plastics pipe 12 for limiting the lumen 9 in this region.

Fig. 4 shows detail X of Fig. 1 more clearly.

The outer pipe 12 surrounds a transitional portion 15 between the reinforcing pipe 11 and the adjacent inner plastics pipe 13. Said transitional portion 15 is provided with a kink protection 14 being formed in this example as a case 16.

As an alternative to the embodiments of Figs. 1 to 4, it is conceivable that the portion 10 as a whole is formed as a metal pipe, i. e. not consisting of two concentric pipes, as shown in Figs. 3 and 4. In this case, the metal pipe 11 has a massive cross section in which a longitudinal borehole is made for forming the lumen 8 and an adjacent borehole is made for forming the lumen 9. In another embodiment which is basically conceivable, the plastics pipe (which would correspond to the portion 17 being designated with a dotted arrow in Fig. 1) ensuing the metal pipe is also formed as a pipe with a massive cross section, in which corresponding boreholes are provided for the continuation of lumen 8 or 9.